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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,665	09/28/2000	Sudhirdas K. Prayaga	15966-572	8095

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EXAMINER
WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/672,665	PRAYAGA ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached sheet(s).

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached sheet(s)*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1,29,32 and 44-46*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ATTACHMENT TO ADVISORY ACTION

3. cont. The applicant's reply has overcome the rejection of claims 1-4, 23-24, 29, 32, 35, and 42 under 35 U.S.C. 112, first paragraph, for lack of written description. The applicant's reply has also overcome the rejection of claims 1-4, 22-23, 29, and 32 under 35 U.S.C. 112, second paragraph.

5. cont. The rejection of claims 1, 29 and 32 under 35 U.S.C. 112, first paragraph, for lack of enablement is maintained and extended to include new claims 44-46. Applicant's arguments have been fully considered but do not overcome the grounds of rejection of reasons of record as discussed briefly below.

The applicant argues that SEQ ID NO:1 is highly homologous to the prothymosin family and therefore the skilled artisan would recognize that the polypeptide corresponding to SEQ ID NO:2 would function as an immunomodulatory molecule. In response, regarding the disclosed homology between SEQ ID NO:2 and human prothymosin α , the previous office actions have stated that the art at the time of filing teaches that the human prothymosin α gene family contains 6 known members. Of these, only **one** gene contains introns and is expressed in two alternately spliced forms, whereas the other 5 are considered pseudogenes whose expression has not been conclusively established (Pineiro et al.). The 6 known prothymosin α genes are highly conserved and share greater than 95% sequence homology. The previous office actions also stated that Pineiro et al. teaches that the determination of pseudogene transcription and expression of the

putative protein products of the pseudogenes is complicated by the degree of genomic conservation and apparent absence of size heterogeneity (Piniero et la., page 1436, column 2). Thus, based on the teachings of the art at the time of filing, the skilled artisan would not have been able to predict that a gene sequence with a high degree of homology to human prothymosin α would in fact encode a functional human prothymosin α polypeptide. The specification further provides no evidence that the polypeptide encoded by SEQ ID NO:1, or the amino acid sequence of SEQ ID NO:2 is capable of mediating any effect on cellular proliferation or capable of mediating any type of immunomodulatory activity. Therefore, in view of the lack of guidance concerning any biological property of a protein corresponding to the amino acid sequence of SEQ ID NO:2 or encoded by SEQ ID NO:1, the absence of evidence in the specification that the amino acid sequence of SEQ ID NO:2 shares any biological activities in common with prothymosin α, the presence of numerous unexpressed pseudogenes in the prothymosin α gene family, and the lack of guidance as to functional domains and amino acids critical for biological activity in the putative protein of SEQ ID NO:2, it would have required undue experimentation to determine whether a protein with an amino acid sequence comprising or consisting of SEQ ID NO:2 would have any type of biological activity in cells *in vitro* or *in vivo*.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER